

of Merideth (U.S. Patent No. 6,164,277). Claim 6 was rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Drost et al. and Merideth in further view of Bernstein et al. (U.S. Patent No. 5,163,421). Claims 7, 8, 16 and 23 were rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Drost et al. and Merideth and further in view of Ben-Haim (U.S. Patent No. 6,083,170) and Lemelson (U.S. Patent No. 5,845,646). Claims 9, 10, 17, 18 and 24 were rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Drost et al. and Merideth and further in view of Ben-Haim and Flesch (U.S. Patent No. 5,681,263). Claim 27 was not specifically rejected. Applicants respectfully request reconsideration of claims 1-27, including independent claims 1, 11 and 19.

Independent claim 1 requires a memory-less adaptable section operable to maintain the position of the handle section relative to the transducer section without steering wires. Neither of Drost et al. and Merideth disclose these limitations.

Drost et al., like previous references relied on by the Examiner and now no longer used for rejections, use a guide wire to position the transducer (col. 3, lines 4-11). A guide wire made of stainless steel or the like is within the flexible portion 16 (col. 3, lines 10-18). Stainless steel wire is a poor candidate for a material operable to maintain a position of the handle relative to the transducer not as a steering wire. Stainless steel has high yield points, work hardens when deformed and has relatively low resistance to low cycle fatigue cracking. Since Drost et al. disclose the stainless steel as a “guide wire” (not a post or shaft) and in light of the poor performance of stainless steel as a memoryless material, a person of ordinary skill in the art would read Drost et al. as disclosing a guide wire for controlling the position of the transducer while in the patient – a wire that angles the transducer position by pulling or releasing the wire tension. A person of ordinary skill in the art would understand the guide wire to be a steering wire allowing control of the bending but maintaining a bent position based on user operation at the handle. The Examiner alleges that Figure 1 shows the probe being bendable at more than one location, but the flexible portion is disclosed as long enough to permit bending of “a” 90 degree angle (col. 3, lines 15-18). The other bends shown in Figure 1 are part of a “stiff” portion (col. 3, lines 1-3), so are fixed. Drost et al. provide a guide wire for curving the flexible

portion in response to finger pressure. Drost et al. do not suggest a memory-less adaptable or adjustable section to maintain a position without steering wires.

Merideth discloses an embodiment using a steering wire throughout the entire device. The handle 14 is connected to the distal end 18 by a guide member (Figure 1 and col. 5, lines 9-12). The guide member 12 is made of flexible material, malleable material that can be formed into a desired shape, rigid or semi-rigid (col. 5, lines 41-42 and 61-64). An internal angulation wire 26 is provided in the guide member 12 for controlling the distal end 18 relative to the intermediate section 24 (col. 5, lines 42-48). A lever 28 on the handle connects to the angulation wire 26 so that the user may manipulate the distal end 18 (col. 5, lines 52-58). Since the angulation wire 26 extends to the distal end 18 as shown in Figure 1, the element 12 beyond the section 34 includes the angulation wire 26 contrary to the Examiner's assertion. The angulation wire 26 extends throughout the guide member 12. Merideth does not suggest a memory-less adaptable or adjustable section to maintain a position without steering wires.

A person of ordinary skill in the art would not have replaced the transducer of Merideth with the transducer of Drost et al. or combined elements of both to provide the claimed invention. As the motivation to combine, the Examiner relies on: (a) both Drost et al. and Merideth having a transducer housing and adjustable section capable of bending without a wire and (b) Drost et al. disclosing rotating of the axis of the transducer in respect to the handle axis to position the transducer housing within the cavity. However and as discussed above, (a) both Drost et al. and Merideth use guide wires to control the transducer housing. (b) The rotation of the axis of the transducer in respect to the handle axis to position the transducer housing within the cavity of Drost et al. is based on the rigid, angular stiff portion, so does not suggest the combination of teachings. Furthermore, the transducer of Merideth is used for generating sound signals for intubation. Merideth discloses that fiber optics are used for visual guidance. A person of ordinary skill in the art would not have used a transducer array of Drost et al., but would have used fiber optics as suggested by Merideth. Finally, Merideth is directed to the much different purpose and art of intubation stylets – a specific application. Drost et al. provide a stiff portion with angular offsets to avoid the hand of the surgeon from blocking the view. Such a stiff portion would interfere with intubation, so a person of ordinary skill in the art

would not have used the probe body of Drost et al. with the intubation device of Merideth or vice versa.

Independent claim 11 requires an adjustable section having a device to maintain an adjusted bent position without a device for adjusting the adjustable section during use within the patient. As discussed above, both Drost et al. and Merideth include steering wires or other mechanism to allow adjustment of the bend within the patient. Merideth uses an angulation wire with a level on the handle for positioning the distal end. Drost et al. provides a stiff or not adjustable section attached to the flexible portion with a stainless steel guide wire. Drost et al. and Merideth do not suggest an adjustable section device to maintain a bent position without a device for adjustment during use within the patient.

Claim 19 requires rotating a first axis of a transducer housing relative to second axis of a handle housing prior to inserting the probe into a cavity of a patient and maintaining a relative position while the transducer housing is within the cavity. As discussed above, Drost et al. and Merideth disclose steering wires or other alignment mechanisms for changing the position of the transducer while inserted into the patient. Merideth provides an angulation wire with a lever control on the handle for positioning the sensor head while in the cavity (see col. 3, lines 34-37 and col. 4, lines 4-20). As discussed above, Drost et al. suggest a guide wire as well. Drost et al. uses the guide wire for positioning the wire with finger pressure (col. 3, lines 8-10) and Merideth also uses finger or thumb motion on the lever on the handle to move the angulation wire (col. 5, lines 52-58). Neither reference suggests rotating a first axis of a transducer housing relative to second axis of a handle housing prior to inserting the probe into a cavity of a patient and maintaining a relative position while the transducer housing is within the cavity.

Dependent claims 2-5, 12-15, 20-22, and 25-27 depend from the independent claims 1, 11 and 19 discussed above. Accordingly, these dependent claims are allowable for the reasons discussed above for the independent claims. Further limitations of the dependent claims distinguish these claims from Drost et al. and Merideth. For example, Drost et al. and Merideth

do not disclose: the adaptable section comprising a memoryless bendable section as claimed in claims 4 and 14; increasing the malleability in response to external force as claimed in claims 25 and 26; maintaining the spatial orientation of the transducer section to the handle section free of change during use in the cavity as claimed in claim 27.

Dependent claim 6 depends from the independent claim 1 discussed above, so is allowable for the reasons discussed above for independent claim 1. Claim 6 is also allowable because a person of ordinary skill in the art would not have been motivated to use the aluminum tip of Bernstein with the probes of Merideth or Drost et al. Bernstein use therapeutic ultrasound transmitted from the tip of the device for angioplasty (col. 2, lines 6-15 and col. 2, lines 24-40). Aluminum alloys are used on the extreme tip due to good acoustic energy transmission qualities for application of the therapeutic ultrasound (col. 2, lines 29-55 and col. 6, lines 1-56). Merideth and Drost et al. rely on angulation wires or guide wires for controlling the curvature between a handle and transducer to position the transducer. A person of ordinary skill in the art would not have used the aluminum tip of Bernstein as part of the much different steerable section between the handle and the transducer. The acoustic transmission properties of the steering portion between the handle and transducer do not matter for the probes of Merideth and Drost et al. Furthermore, the Examiner relies on the motivation from all three references to provide flexible catheter, yet claims 1 and 6 require maintaining the position of the handle to the transducer. A person of ordinary skill in the art would not have combined these three references to provide the invention of claims 1 and 6 and such combination would be inoperable.

Dependent claims 7, 8, 16 and 23 depend from the independent claims 1, 11 and 19 discussed above, so are allowable for the reasons discussed above for the independent claims. These dependent claims are also allowable for another reason. A person of ordinary skill in the art would not have used the ball and socket joints of Lemelson with the teachings of Ben-Haim, Merideth and Drost et al. Lemelson teaches away from using the ball and socket joints. Steering wires are connected with each ball and socket joint within the catheter (col. 13, lines 19-27). Lemelson notes that "steering systems of the foregoing types [including the ball and socket joints] require internal pull wires or other internal structures which occupy space within the lumen of the catheter. Desirably, however, the catheter diameter should be as small as

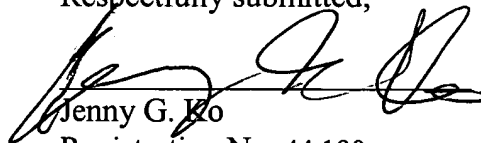
possible to minimize insertion trauma and unwanted damage to surrounding tissue” (col. 13, lines 54-59). Lemelson provides an alternative using magnets (col. 13, lines 60-64). Lemelson teaches away from using the ball and socket joints due to the size requirements, so a person of ordinary skill in the art would not have used the ball and socket joints of Lemelson with the probe teachings of Ben-Haim. Likewise, Lemelson teaches away from using the angulation or guide wires of Merideth and Drost et al.

Dependent claims 9, 10, 17, 18 and 24 depend from the independent claims 1, 11 and 19 discussed above, so are allowable for the reasons discussed above for the independent claims. Claims 9, 10 and 17 require the latch to be part of the adaptable section between the handle and the transducer. The ball latches 34 and indentations 36 of Flesch are part of the handle, not between the handle and transducer. A person of ordinary skill in the art would not have used a rotatable control using the ball latches 34 in the handle as part of the separate bending or steered section of Ben-Haim, Merideth or Drost et al.

CONCLUSION:

Applicants respectfully submit that all of the pending claims are in condition for allowance and seeks early allowance thereof. If for any reason, the Examiner is unable to allow the application but believes that an interview would be helpful to resolve any issues, he is respectfully requested to call the undersigned at (650) 694-5810 or Craig Summerfield at (312) 321-4726.

Respectfully submitted,


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